United States Court of Appeals for the Federal Circuit

INCYTE CORPORATION, INCYTE HOLDINGS CORP.,
Plaintiffs-Appellees

v.

SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMACEUTICAL INDUSTRIES, INC.,
Defendants-Appellants

2025-1162

Appeal from the United States District Court for the District of New Jersey in No. 2:24-cv-06944-JXN-JBC, Judge Julien X. Neals.

Decided: May 7, 2025

MARK J. FELDSTEIN, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, argued for plaintiffs-appellees. Also represented by DANIELLE ANDREA DUSZCZYSZYN, DANIEL F. ROLAND, JASON LEE ROMRELL; J. DEREK MCCORQUINDALE, Reston, VA; MEGAN MEYERS, MARTIN DAVID WEINGARTEN, Atlanta, GA.

PAUL E. TORCHIA, Gibson, Dunn & Crutcher LLP, New York, NY, argued for defendants-appellants. Also represented by CHARLOTTE JACOBSEN, JOSH KREVITT; BLAINE H.

EVANSON, Irvine, CA; ALEXANDER N. HARRIS, Los Angeles, CA; CHRISTINE RANNEY, Denver, CO.

Before MOORE, *Chief Judge*, PROST and HUGHES, *Circuit Judges*.

MOORE, *Chief Judge*.

Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, Sun) appeal an order from the United States District Court for the District of New Jersey granting Incyte Corporation and Incyte Holdings Corporation's (collectively, Incyte) motion for a preliminary injunction enjoining Sun from making, using, selling, advertising, or distributing its drug Leqselvi. On April 9, 2025, we issued an order vacating the injunction with an opinion to follow. For the following reasons, we reverse the district court's order.

BACKGROUND

Incyte owns U.S. Patent No. 9,662,335, which claims deuterated versions of ruxolitinib, a Janus kinase (JAK) modulator used to treat diseases associated with autoimmune disorders. '335 patent at Abstract, 32:60–64, 68:4–9, 109:1–110:38. Claim 1 is representative:

> 1. A compound, which is 3-cyclopentyl-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]propanenitrile, wherein one or more hydrogen atoms are replaced by deuterium; or a pharmaceutically acceptable salt thereof.

Id. at 366:14–17.

In July 2024, Sun secured FDA approval for an oral deuterated ruxolitinib product, branded as Leqselvi, to treat alopecia areata (AA). J.A. 3. Sun was set to launch Leqselvi in October 2024. J.A. 3–4. Prior to launching, Incyte sued Sun for allegedly infringing the '335 patent and

moved for a preliminary injunction. J.A. 1801–42. The district court granted Incyte's motion for a preliminary injunction. J.A. 1–52. Sun appeals. We have jurisdiction pursuant to 28 U.S.C. §§ 1292(c)(1) and 1295(a)(1).

DISCUSSION

I.

We review the grant of a preliminary injunction according to the law of the regional circuit, here the Third Circuit, except for patent-specific issues, which we review according to Federal Circuit law. *Koninklijke Philips N.V. v. Thales DIS AIS USA LLC*, 39 F.4th 1377, 1379 (Fed. Cir. 2022). The grant of a preliminary injunction is reviewed for an abuse of discretion. *Id.* A district court abuses its discretion when it makes a clear error of judgment in weighing relevant factors or exercises its discretion based upon an error of law or a clearly erroneous factual finding. *Id.*

To obtain a preliminary injunction, a party must show "that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1352 (Fed. Cir. 2016) (alterations in original) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). A district court's finding of irreparable harm is reviewed to determine whether it is clearly erroneous. *See Ferring Pharms., Inc. v. Watson Pharms., Inc.*, 765 F.3d 205, 218 (3d Cir. 2014); *Whitaker By Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1045 (7th Cir. 2017); *Texas v. United States Dep't of Homeland Sec.*, 123 F.4th 186, 211 (5th Cir. 2024); *Sleep No. Corp. v. Young*, 33 F.4th 1012, 1018 (8th Cir. 2022).

Sun appeals the district court's grant of a preliminary injunction, arguing Incyte failed to show it is likely to (1) suffer irreparable harm and (2) succeed on the merits.

Appellant Br. 22–58. Because the district court clearly erred in its irreparable harm analysis, we do not reach Sun's likelihood of success arguments.

II.

A patentee can be irreparably harmed by an alleged infringer's improper "head start" and the loss of the "first mover advantage" because the alleged infringer can capture market share and secure a competitive lead. *Bio-Rad Lab'ys, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1378 (Fed. Cir. 2020); John C. Jarosz, Jorge L. Contreras & Robert L. Vigil, *Preliminary Injunctive Relief in Patent Cases: Repairing Irreparable Harm*, 31 TEX. INTELL. PROP. L.J. 63, 124–25 (2022) ("A first mover advantage can be thought of as a firm's benefits from being the first to market a new product or service. . . . [L]oss of a first mover advantage [can include] possible harm related to the loss of 'sticky' customer relationships."). This economic principle can apply in the medical context when patients are unlikely to switch treatments. *See Natera, Inc. v. NeoGenomics Lab'ys, Inc.*, 106 F.4th 1369, 1379 (Fed. Cir. 2024) (noting that "continuity of care" for patients supports finding irreparable harm based on infringing competitor's plan to enter the market). In this case, it is undisputed patients are unlikely to switch treatments for AA. Appellee Br. 43; Dkt. 5 (Sun Motion to Expedite Appeal) at 13–14 (citing J.A. 9951 ¶ 52 and J.A. 16851 ¶ 97).

Before the district court, Incyte provided five alternative theories for irreparable harm. J.A. 1829–42. Incyte's last theory, which it spent just two paragraphs developing, was that Sun's Leqselvi launch would give Sun an unjust head start over Incyte in the AA market. J.A. 1841–42. Incyte argued the head start would give Sun a longer lead time and diminish the value of Incyte's topical deuterated ruxolitinib product currently in the early stages of development. J.A. 1841–42; J.A. 10575, 10588. The district court agreed with Incyte's head start theory for its finding of

irreparable harm, expressly rejecting Incyte's other theories. J.A. 26–45. The district court explained that "but for Sun's Leqselvi, Incyte's '335 patent would provide it with the ability to bring a [deuterated ruxolitinib] AA treatment *first to market*." J.A. 41 (emphasis added). Accepting Incyte's assertions regarding the development of its product, there is no question this is a clearly erroneous fact finding.

The facts are undisputed. Sun is prepared to launch. Oral Arg. 21:55–22:04.[1] The '335 patent expires in December 2026. And Incyte will not launch its product, under its best-case scenario, until at least several years after its '335 patent expires.[2] J.A. 4 n.8; Appellee Br. 8. Because Incyte cannot enjoin Sun from launching after its '335 patent expires, Sun's multi-year head start is inevitable regardless of any injunction. *Natera*, 106 F.4th at 1378 (stating the party seeking an injunction must "show it is likely to suffer irreparable harm if the injunction is not granted").

It was clearly erroneous for the district court to find that Incyte would be first to market if its preliminary injunction were granted. At best, Incyte argues that, without the injunction, Sun will receive an additional two years on the market and cause Incyte irreparable harm due to its loss of market share from this *extended* head start. Oral Arg. at 13:29–13:55; Appellee Br. 43 ("An advantage of even a few more years permits Sun to entrench itself

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[1] Available at https://oralarguments.cafc.uscourts.gov/dfault.aspx?fl=25-1162_04092025.mp3.

[2] Incyte provides two development timelines that show different projected dates on which Incyte anticipates filing a new drug application (NDA). *Compare* J.A. 10575, *with* J.A. 10588. Counsel for Incyte believes the timeline with the earlier projected NDA date is correct but could not confirm. Oral Arg. at 16:19–19:08. Even assuming the earlier projected date is correct, FDA approval would still not occur until several years after the '335 patent expires.

intractably in the market . . . causing unquantifiable harm by locking up patients who will be lost to Incyte 'forever.'" (quoting J.A. 6805 ¶¶ 66–67)). Incyte fails to provide non-speculative evidence that it will be irreparably harmed by Sun's launch under these circumstances where Sun's multi-year head start is inevitable.

Incyte argues the district court independently found irreparable harm under its head start theory based on the diminished value to Incyte's investment in developing its product. Appellee Br. 16–17; Oral Arg. 8:45–9:45 (citing district court's order at J.A. 43, 49). The district court's irreparable harm findings regarding investment-based harm hinged on the same mistake of fact that its head start finding was predicated on—that, absent an injunction, Incyte would be first to market. J.A. 41, 43 ("Sun's premature entrance into the AA market diminishes the value of [Incyte]'s investments in a topical AA product."). For the same reasons, the district court's finding regarding irreparable harm is clearly erroneous.

We hold that the district court clearly erred in finding that Incyte established irreparable harm. We reverse the district court's grant of the preliminary injunction.

REVERSED

COSTS

Costs to Sun.